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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,871	08/02/2001	Robert L. Rykhus JR.	687-437	5424

7590 02/06/2004  
JEFFREY J. HOHENSHELL  
AMS RESEARCH CORPORATION  
10700 BREN ROAD WEST  
MINNETNKA, MN 55343

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/920,871

Applicant(s)

RYKHUS ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 26-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 26-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.

Claims 1-3, 8-11, 16-25 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789). Hogan discloses a bioabsorbable self-expanding stent (col. 5, lines 50-66) comprising a cylindrical sleeve (e.g. 21) including a latticed network formed from a plurality of monofilaments 22, 26 braided in an alternating braid pattern (col. 5, lines 49-50) which comprise at least one biocompatible polymer (col. 2, lines 46-67), said cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Further, the in vivo lifetime is inherently "controllable" as claimed since it is controlled or determined at the time of manufacture by factors such as the size of the sleeve, the specific choice of bioabsorbable material, whether or not it is exposed to gamma radiation (and how much), noting that the Hogan stent is inherently capable of being exposed to gamma radiation. Hogan fails to disclose the stent as being annealed and gamma-irradiated. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be

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annealed in order to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan filaments so that the Hogan stent too would have this advantage. Further, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be gamma-irradiated in order to control the rate that the stent degrades (page 19, lines 24-28). It would have been obvious to irradiate the Hogan filaments so that the Hogan stent too would have this advantage. As to claims 2, 3, 10, 11, and 17, Hogan fails to disclose the specific number of monofilaments claimed. However, it was well known in this art to use a large number of filaments for a stent and to choose a number which optimizes the desired expansion force and size of the stent. It would have been obvious to use the specific number of monofilaments claimed for the Hogan stent so that it would have these advantages. As to claims 20-23 and 25, Hogan fails to disclose the specific diameter claimed. However, it was well known in this art to size stents as with the specific diameter claimed so that it fits a correspondingly sized blood vessel. It would have been obvious to size the Hogan stent as claimed so that it would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions

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(M.P.E.P. 2144.03). As to claim 19, Hogan discloses polydioxanone in col. 2, line 58.

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) as applied to claims 1 and 11 above, and further in view of Amstrup (5,476, 508). Hogan fails to disclose a single strand shift in the braid. However, Amstrup teaches that braiding in a stent should include a single strand shift (at 12) in order to interlock the weave and apparently guarantee a stable crossing region which can accept large restoring forces (col. 4, lines 7-21). It would have been obvious to include a single strand shift in the Hogan braid so that it too would have this advantage.

Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) as applied to claims 1 and 9 above, and further in view of Thompson et al. (5,957,974). Hogan fails to disclose the claimed braid angle. However, Thompson et al. teach that the braid angle for a self-expanding stent should be 60-150 and preferably 90-100 degrees (col. 7, lines 21-22) apparently in order to optimize the amount of shortening (col. 7, lines 24-35). It would have been obvious to use this braid angle in the Hogan braid so that it too would have this advantage.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) as applied to claim 1 above, and further in view of Turnlund et al. (5,629,077). Hogan fails to disclose an under-two-over-two braid pattern. However, Turnlund et al. teach that the braid pattern for a stent should be under-two-over-two (col. 5, lines 54-56) apparently in order to obtain the desired strength of the mesh (col. 6, lines 6-9). It would have been obvious to use this braid pattern in the Hogan stent so that it too would have this advantage.

Applicant's arguments with respect to claims 1-25, 50 and 51 have been considered but are moot in view of the new ground(s) of rejection. As to the "fenestrated" wall surface defined in claims 22-25, for example, the openings between the threads of the Hogan stent are fenestrations, making the wall "fenestrated", as broadly claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

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action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
2/5/04



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731